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## **FREEDOM OF INFORMATION SUMMARY**

**ANTIROBE Capsules  
(clindamycin hydrochloride)**

**Supplemental NADA 120-161  
Pharmacia & Upjohn Co.**

**Addition of a Dose Range for Dogs  
Addition of a 300 mg Capsule  
Addition of Recent MIC Data**

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## 1. GENERAL INFORMATION

- a. *File Number:* NADA 120-161
- b. *Sponsor:* Pharmacia & Upjohn Co.  
7000 Portage Road  
Kalamazoo, MI 49001-0199  
Drug Labeler Code: 000009
- c. *Established Name:* clindamycin hydrochloride
- d. *Proprietary Name:* ANTIROBE Capsules
- e. *Dosage Form:* capsules
- f. *How Supplied:* The product is available as follows:  
  
25 mg – bottles of 600  
75 mg – bottles of 200  
150 mg – bottles of 100  
150 mg – blister packages of 100  
300 mg – blister packages of 100 (new)
- g. *How Dispensed:* Prescription (Rx) – US Federal law restricts this drug to use by, or on the order of, a licensed veterinarian.
- h. *Amount of Active Ingredients:* Each capsule (4 strengths) contains the equivalent of 25, 75, 150, and 300 mg of clindamycin hydrochloride
- i. *Route of Administration:* oral
- j. *Species/Class:* dogs
- k. *Recommended Dosage:* The drug is administered at a dose range of 2.5-15 mg/lb every 12 hours for skin infections (wounds and abscesses), deep wounds and abscesses, and dental infections for a maximum of 28 days. The drug is also administered at a dose range of 5.0-15 mg/lb every 12 hours for osteomyelitis for a minimum of 28 days.

l. *Pharmacological Category:*

antibiotic

m. *Indications:*

ANTIROBE Capsules (brand of clindamycin hydrochloride) are indicated for the treatment of infections in dogs caused by susceptible strains of the designated microorganisms in the specific conditions listed below:

**Skin infections (wounds and abscesses)** due to coagulase positive staphylococci (*Staphylococcus aureus* or *Staphylococcus intermedius*).

**Deep wounds and abscesses** due to *Bacteroides fragilis*, *Prevotella melaninogenicus*, *Fusobacterium necrophorum* and *Clostridium perfringens*.

**Dental infections** due to *Staphylococcus aureus*, *Bacteroides fragilis*, *Prevotella melaninogenicus*, *Fusobacterium necrophorum* and *Clostridium perfringens*.

**Osteomyelitis** due to *Staphylococcus aureus*, *Bacteroides fragilis*, *Prevotella melaninogenicus*, *Fusobacterium necrophorum* and *Clostridium perfringens*.

n. *Effect of Supplement:*

The supplement provides for the use of clindamycin hydrochloride (ANTIROBE Capsules) in dogs at a dose range of 2.5-15 mg/lb body weight every 12 hours for skin infections (wounds and abscesses), deep wounds and abscesses, and dental infections. It also provides for a dose range in dogs of 5-15 mg/lb every 12 hours for osteomyelitis. In addition, this supplement provides for the addition of a 300 mg capsule. This supplement also provides for the addition of recent MIC data derived from U.S. diagnostic laboratories.

## 2. EFFECTIVENESS

Please refer to the Freedom of Information (FOI) Summaries for ANTIROBE Capsules (clindamycin hydrochloride), NADA 120-161, dated June 6, 1984 and November 16, 1989. This approval does not affect this section of these summaries, however, a review

of this data supports the lower ends of the two dose ranges of 2.5-15 mg/lb and 5-15mg/lb body weight every 12 hours in dogs.

### **3. TARGET ANIMAL SAFETY**

Please refer to the Freedom of Information (FOI) Summary for ANTIROBE Capsules (clindamycin hydrochloride), NADA 120-161, dated June 6, 1984. This approval does not affect this section of the summary, however, a review of this data supports the upper end of the two dose ranges of 2.5-15 mg/lb and 5-15 mg/lb body weight every 12 hours for up to a maximum of 28 days in dogs.

### **4. HUMAN SAFETY**

This drug is intended for use in dogs, which are non-food animals. Because this new animal drug is not intended for use in food-producing animals, data on human safety pertaining to drug residues in food were not required for approval of this NADA.

Human Warnings are provided on the product label as follows: "WARNING: Keep out of reach of children. Not for human use."

### **5. AGENCY CONCLUSIONS**

The data submitted in support of this supplemental NADA satisfy the requirements of Section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR 514 of the implementing regulations. The data demonstrates that ANTIROBE Capsules (clindamycin hydrochloride), when administered to dogs, are safe and effective when used under labeled conditions.

The drug is restricted to use by or on the order of a licensed veterinarian because professional expertise is judged to be critical in the diagnosis of bacterial infections in animals, treatment of these conditions, and monitoring for possible adverse effects of the drug.

Under the Center's supplemental approval policy 21 CFR 514.106(b)(2), this is a Category II change.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act, this approval for non-food producing animals does not qualify for marketing exclusivity because the supplemental application does not contain substantial evidence of the effectiveness of the drug involved, or any studies of animal safety required for the approval and conducted or sponsored by the applicant.

## **6. APPROVED PRODUCT LABELING**

Facsimile Labeling is attached as indicated below:

Package insert

Bottle labels (25 mg, 75 mg, 150 mg)

Blister package labels (150 mg, 300 mg)

Blister package box labels (150 mg, 300 mg)

## Antirobe®

brand of clindamycin  
hydrochloride capsules, USP

## Antirobe Aquadrops®

brand of clindamycin hydrochloride liquid

Pharmacia  
&Upjohn

## Antirobe

brand of clindamycin hydrochloride capsules, USP

## Antirobe Aquadrops

brand of clindamycin hydrochloride liquid

**Caution:** Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

### DESCRIPTION

ANTIROBE Capsules and ANTIROBE AQUADROPS Liquid contain clindamycin hydrochloride which is the hydrated salt of clindamycin. Clindamycin is a semisynthetic antibiotic produced by a 7(S)-chlorosubstitution of the 7(R)-hydroxyl group of a naturally produced antibiotic produced by *Streptomyces lincolnensis* var. *lincolnensis*.

**ANTIROBE Capsules (For Use in Dogs Only):**  
**25 mg Capsule**, each yellow and white capsule contains clindamycin hydrochloride equivalent to 25 mg of clindamycin.

**75 mg Capsule**, each green capsule contains clindamycin hydrochloride equivalent to 75 mg of clindamycin.

**150 mg Capsule**, each light blue and green capsule contains clindamycin hydrochloride equivalent to 150 mg of clindamycin.

**300 mg Capsule**, each light blue capsule contains clindamycin hydrochloride equivalent to 300 mg of clindamycin.

**ANTIROBE AQUADROPS Liquid (For Use in Dogs and Cats)** is a palatable formulation intended for oral administration. Each mL of ANTIROBE AQUADROPS Liquid contains clindamycin hydrochloride equivalent to 25 mg clindamycin; and ethyl alcohol, 8.64%.

### ACTIONS

**Site and Mode of Action:** Clindamycin is an inhibitor of protein synthesis in the bacterial cell. The site of binding appears to be in the 50S sub-unit of the ribosome. Binding occurs to the soluble RNA fraction of certain ribosomes, thereby inhibiting the binding of amino acids to those ribosomes. Clindamycin differs from cell wall inhibitors in that it causes irreversible modification of the protein-synthesizing subcellular elements at the ribosomal level.

**MICROBIOLOGY:** Clindamycin is a lincosamide antimicrobial agent with activity against a wide variety of aerobic and anaerobic bacterial pathogens. Clindamycin is a bacteriostatic compound that inhibits bacterial protein synthesis by binding to the 50S ribosomal subunit. The minimum inhibitory concentrations (MICs) of Gram-positive and obligate anaerobic pathogens isolated from dogs and cats in the United States are presented in Table 1 and Table 2. Bacteria were isolated in 1998-1999. All MICs were performed in accordance with the National Committee for Clinical Laboratory Standards (NCCLS).

## Antirobe

brand of clindamycin hydrochloride capsules, USP

## Antirobe Aquadrops

brand of clindamycin hydrochloride liquid

Table 1. Clindamycin MIC Values ( $\mu\text{g/mL}$ ) from Diagnostic Laboratory Survey Data Evaluating Canine Pathogens in the U.S. during 1998-99<sup>1</sup>

Organism	Number of Isolates	MIC <sub>50</sub>	MIC <sub>85</sub>	MIC <sub>90</sub>	Range
<b>Soft Tissue/Wound<sup>2</sup></b>					
<i>Staphylococcus aureus</i>	17	0.5	0.5	$\geq 4.0$	0.25- $\geq 4.0$
<i>Staphylococcus intermedius</i>	28	0.25	0.5	$\geq 4.0$	0.125- $\geq 4.0$
<i>Staphylococcus spp.</i>	18	0.5	0.5	$\geq 4.0$	0.25- $\geq 4.0$
Beta-hemolytic streptococci	46	0.5	0.5	$\geq 4.0$	0.25- $\geq 4.0$
<i>Streptococcus spp.</i>	11	0.5	$\geq 4.0$	$\geq 4.0$	0.25- $\geq 4.0$
<b>Osteomyelitis/Bone<sup>3</sup></b>					
<i>Staphylococcus aureus</i>	20	0.5	0.5	0.5	0.5 <sup>4</sup>
<i>Staphylococcus intermedius</i>	15	0.5	$\geq 4.0$	$\geq 4.0$	0.25- $\geq 4.0$
<i>Staphylococcus spp.</i>	18	0.5	$\geq 4.0$	$\geq 4.0$	0.25- $\geq 4.0$
Beta-hemolytic streptococci	21	0.5	2.0	2.0	0.25- $\geq 4.0$
<i>Streptococcus spp.</i>	21	$\geq 4.0$	$\geq 4.0$	$\geq 4.0$	0.25- $\geq 4.0$
<b>Dermal/Skin<sup>5</sup></b>					
<i>Staphylococcus aureus</i>	25	0.5	$\geq 4.0$	$\geq 4.0$	0.25- $\geq 4.0$
<i>Staphylococcus intermedius</i>	48	0.5	$\geq 4.0$	$\geq 4.0$	0.125- $\geq 4.0$
<i>Staphylococcus spp.</i>	32	0.5	$\geq 4.0$	$\geq 4.0$	0.25- $\geq 4.0$
Beta-hemolytic streptococci	17	0.5	0.5	0.5	0.25-0.5

<sup>1</sup> The correlation between the *in vitro* susceptibility data and clinical response has not been determined.

<sup>2</sup> Soft Tissue/Wound: Includes samples labeled wound, abscess, aspirate, exudates, draining tract, lesion, and mass

<sup>3</sup> Osteomyelitis/Bone: Includes samples labeled bone, fracture, joint, tendon

<sup>4</sup> No range, all isolates yielded the same value

<sup>5</sup> Dermal/Skin: Includes samples labeled skin, skin swab, biopsy, incision, lip

## Antirobe

brand of clindamycin hydrochloride capsules, USP

## Antirobe Aquadrops

brand of clindamycin hydrochloride liquid

Table 2. Clindamycin MIC Values ( $\mu\text{g/mL}$ ) from Diagnostic Laboratory Survey Data Evaluating Feline Pathogens from Wound and Abscess Samples in the U.S. during 1998<sup>1</sup>

Organism	Number of Isolates	MIC <sub>50</sub>	MIC <sub>80</sub>	Range
<i>Bacteroides/Prevotella</i>	30	0.06	4.0	$\leq 0.015$ -4.0
<i>Fusobacterium spp.</i>	17	0.25	0.25	$\leq 0.015$ -0.5
<i>Peptostreptococcus spp.</i>	18	0.13	0.5	$\leq 0.015$ -8.0
<i>Porphyromonas spp.</i>	13	0.06	0.25	$\leq 0.015$ -8.0

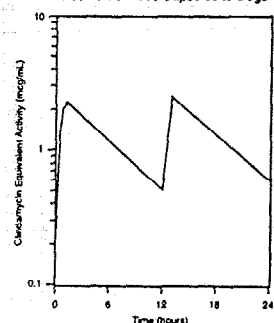
<sup>1</sup> The correlation between the *in vitro* susceptibility data and clinical response has not been determined.

### PHARMACOLOGY

**Absorption:** Clindamycin hydrochloride is rapidly absorbed from the canine and feline gastrointestinal tract.

**Dog Serum Levels:** Serum levels at or above 0.5  $\mu\text{g/mL}$  can be maintained by oral dosing at a rate of 2.5 mg/lb of clindamycin hydrochloride every 12 hours. This same study revealed that average peak serum concentrations of clindamycin occur 1 hour and 15 minutes after oral dosing. The elimination half-life for clindamycin in dog serum was approximately 5 hours. There was no bioactivity accumulation after a regimen of multiple oral doses in healthy dogs.

Clindamycin Serum Concentrations  
2.5 mg/lb (5.5 mg/kg) After B.I.D. Oral  
Dose of Antirobe Capsules to Dogs



## Antirobe

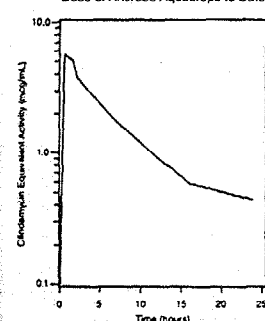
brand of clindamycin  
hydrochloride capsules, USP

## Antirobe Aquadrops

brand of clindamycin  
hydrochloride liquid

**Cat Serum Levels:** Serum levels at or above 0.5  $\mu\text{g/mL}$  can be maintained by oral dosing at a rate of 5 mg/lb of clindamycin hydrochloride liquid every 24 hours. The average peak serum concentration of clindamycin occurs approximately 1 hour after oral dosing. The elimination half-life of clindamycin in feline serum is approximately 7.5 hours. In healthy cats, minimal accumulation occurs after multiple oral doses of clindamycin hydrochloride, and steady-state should be achieved by the third dose.

Clindamycin Serum Concentrations  
5 mg/lb (11 mg/kg) After Single Oral  
Dose of Antirobe Aquadrops to Cats



### METABOLISM AND EXCRETION

Extensive studies of the metabolism and excretion of clindamycin hydrochloride administered orally in animals and humans have shown that unchanged drug and bioactive and bioinactive metabolites are excreted in urine and feces. Almost all of the bioactivity detected in serum after ANTIROBE product administration is due to the parent molecule (clindamycin). Urine bioactivity, however, reflects a mixture of clindamycin and active metabolites, especially N-dimethyl clindamycin and clindamycin sulfoxide.

### ANIMAL SAFETY SUMMARY

**Rat and Dog Data:** One year oral toxicity studies in rats and dogs at doses of 30, 100 and 300 mg/kg/day (13.6, 45.5 and 136.4 mg/lb/day) have shown clindamycin hydrochloride capsules to be well tolerated. Differences did not occur in the

Antirobe  
clindamycin hydrochloride  
capsules, USP  
Antirobe Aquadrops  
clindamycin  
hydrochloride liquid

1125085180



Antirobe  
clindamycin hydrochloride  
capsules, USP  
Antirobe Aquadrops  
clindamycin  
hydrochloride liquid



0813805711

## Antirobe®

brand of clindamycin hydrochloride capsules, USP

## Antirobe Aquadrops®

brand of clindamycin hydrochloride liquid

parameters evaluated to assess toxicity when comparing groups of treated animals with contemporary controls. Rats administered clindamycin hydrochloride at 600 mg/kg/day (272.7 mg/lb/day) for six months tolerated the drug well; however, dogs orally dosed at 600 mg/kg/day (272.7 mg/lb/day) vomited, had anorexia, and subsequently lost weight. At necropsy these dogs had erosive gastritis and focal areas of necrosis of the mucosa of the gall bladder.

Safety in gestating bitches or breeding males has not been established.

**Cat Data:** The recommended daily therapeutic dose range for clindamycin hydrochloride (ANTIROBE AQUADROPS Liquid) is 11 to 33 mg/kg/day (5 to 15 mg/lb/day) depending on the severity of the condition. Clindamycin hydrochloride (ANTIROBE AQUADROPS Liquid) was tolerated with little evidence of toxicity in domestic shorthair cats when administered orally at 10x the minimum recommended therapeutic daily dose (11 mg/kg; 5 mg/lb) for 15 days, and at doses up to 5x the minimum recommended therapeutic dose for 42 days. Gastrointestinal tract upset (soft feces to diarrhea) occurred in control and treated cats with emesis occurring at doses 3x or greater than the minimum recommended therapeutic dose (11 mg/kg/day; 5 mg/lb/day). Lymphocytic inflammation of the gallbladder was noted in a greater number of treated cats at the 110 mg/kg/day (50 mg/lb/day) dose level than for control cats. No other effects were noted. Safety in gestating queens or breeding male cats has not been established.

### INDICATIONS

ANTIROBE (brand of clindamycin hydrochloride) Capsules (for use in dogs only) and AQUADROPS Liquid (for use in dogs and cats) are indicated for the treatment of infections caused by susceptible strains of the designated microorganisms in the specific conditions listed below:

**Dogs: Skin Infections (wounds and abscesses)** due to coagulase positive staphylococci (*Staphylococcus aureus* or *Staphylococcus intermedius*). **Deep wounds and abscesses** due to *Bacteroides fragilis*, *Prevotella melaninogenica*, *Fusobacterium*

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brand of clindamycin hydrochloride capsules, USP

## Antirobe Aquadrops

brand of clindamycin hydrochloride liquid

*necrophorum* and *Clostridium perfringens*. **Dental Infections** due to *Staphylococcus aureus*, *Bacteroides fragilis*, *Prevotella melaninogenica*, *Fusobacterium necrophorum* and *Clostridium perfringens*. **Osteomyelitis** due to *Staphylococcus aureus*, *Bacteroides fragilis*, *Prevotella melaninogenica*, *Fusobacterium necrophorum* and *Clostridium perfringens*.

**Cats: Skin Infections (wounds and abscesses)** due to *Staphylococcus aureus*, *Staphylococcus intermedius*, *Streptococcus* spp. **Deep wounds and Infections** due to *Clostridium perfringens* and *Bacteroides fragilis*.

**Dental Infections** due to *Staphylococcus aureus*, *Staphylococcus intermedius*, *Streptococcus* spp., *Clostridium perfringens* and *Bacteroides fragilis*.

### CONTRAINDICATIONS

ANTIROBE Capsules and ANTIROBE AQUADROPS Liquid are contraindicated in animals with a history of hypersensitivity to preparations containing clindamycin or lincocyclins.

Because of potential adverse gastrointestinal effects, do not administer to rabbits, hamsters, guinea pigs, horses, chinchillas or ruminating animals.

### WARNINGS

Keep out of reach of children. Not for human use.

### PRECAUTIONS

During prolonged therapy of one month or greater, periodic liver and kidney function tests and blood counts should be performed.

The use of ANTIROBE occasionally results in overgrowth of non-susceptible organisms such as clostridia and yeasts. Therefore, the administration of ANTIROBE should be avoided in those species sensitive to the gastrointestinal effects of clindamycin (see CONTRAINDICATIONS). Should superinfections occur, appropriate measures should be taken as indicated by the clinical situation.

Patients with very severe renal disease and/or very severe hepatic disease accompanied by severe metabolic aberrations should be dosed with caution, and serum clindamycin levels monitored during high-dose therapy.

Clindamycin hydrochloride has been shown to have neuromuscular blocking properties that may enhance the action of other neuromuscular blocking agents. Therefore, ANTIROBE should be used with caution in animals receiving such agents.

Safety in gestating bitches and queens or breeding male dogs and cats has not been established.

### ADVERSE REACTIONS

Side effects occasionally observed in either clinical trials or during clinical use were vomiting and diarrhea.

To report adverse reactions or a suspected adverse reaction call 1-800-793-0596.

## Antirobe

brand of clindamycin hydrochloride capsules, USP

## Antirobe Aquadrops

brand of clindamycin hydrochloride liquid

### DOSAGE AND ADMINISTRATION

#### Dogs:

**Infected Wounds, Abscesses, and Dental Infections**

**Oral:** 2.5-15.0 mg/lb body weight every 12 hours.

**Duration:** Treatment with ANTIROBE products may be continued up to a maximum of 28 days if clinical judgment indicates. Treatment of acute infections should not be continued for more than three or four days if no response to therapy is seen.

#### Dosage Schedule:

##### Capsules

ANTIROBE 25 mg, administer 1-6 capsules every 12 hours for each 10 pounds of body weight.

ANTIROBE 75 mg, administer 1-6 capsules every 12 hours for each 30 pounds of body weight.

ANTIROBE 150 mg, administer 1-6 capsules every 12 hours for each 60 pounds of body weight.

ANTIROBE 300 mg, administer 1-6 capsules every 12 hours for each 120 pounds of body weight.

##### Liquid

ANTIROBE AQUADROPS, administer 1-6 mL/10 lbs body weight every 12 hours.

#### Dogs:

##### Osteomyelitis

**Oral:** 5.0-15.0 mg/lb body weight every 12 hours

**Duration:** Treatment with ANTIROBE is recommended for a minimum of 28 days. Treatment should not be continued for longer than 28 days if no response to therapy is seen.

#### Dosage Schedule:

##### Capsules

ANTIROBE 25 mg, administer 2-6 capsules every 12 hours for each 10 pounds of body weight.

ANTIROBE 75 mg, administer 2-6 capsules every 12 hours for each 30 pounds of body weight.

ANTIROBE 150 mg, administer 2-6 capsules every 12 hours for each 60 pounds of body weight.

ANTIROBE 300 mg, administer 2-6 capsules every 12 hours for each 120 pounds of body weight.

##### Liquid

ANTIROBE AQUADROPS, administer 2-6 mL/10 lbs body weight every 12 hours.

#### Cats:

**Infected Wounds, Abscesses, and Dental Infections**

5.0 - 15.0 mg/lb body weight once every 24 hours depending on the severity of the condition.

**Duration:** Treatment with ANTIROBE AQUADROPS Liquid may be continued up to a

## Antirobe

brand of clindamycin hydrochloride capsules, USP

## Antirobe Aquadrops

brand of clindamycin hydrochloride liquid

maximum of 14 days if clinical judgment indicates. Treatment of acute infections should not be continued for more than three to four days if no clinical response to therapy is seen.

#### Dosage Schedule:

ANTIROBE AQUADROPS, to provide 5.0 mg/lb, administer 1 mL/5 lbs body weight once every 24 hours; to provide 15.0 mg/lb, administer 3 mL/5 lbs body weight once every 24 hours.

### HOW SUPPLIED

ANTIROBE Capsules are available as:

25 mg - bottles of 600 .....NDC 0009-3043-01

75 mg - bottles of 200 .....NDC 0009-3044-01

150 mg - bottles of 100 .....NDC 0009-3045-01

150 mg - blister packages

of 100 .....NDC 0009-3045-08

300 mg - blister packages

of 100 .....NDC 0009-5015-01

NADA #120-161, Approved by FDA

ANTIROBE AQUADROPS Liquid is available as 20 mL filled in 30 mL bottles (25 mg/mL) supplied in packers containing 12 cartoned bottles with direction labels and calibrated dosing droppers. NDC 0009-3179-01. NADA #135-940, Approved by FDA

To report a suspected adverse reaction or to request a material safety data sheet (MSDS), call 1-800-793-0596.

Store at controlled room temperature 20° to 25° C (68° to 77° F) [see USP].

### ANTIROBE AQUADROPS

Made by

Pharmacia & Upjohn Company  
Kalamazoo, MI 49001, USA

ANTIROBE Capsules

Made in Canada for  
Pharmacia & Upjohn Company  
Kalamazoo, MI 49001, USA  
By Patheon YM Inc.  
Don Mills, Ontario, M3B 1Y5  
CANADA

Revised February 2002

813 805 711E

692074

3179-01-000



Approved for use in dogs.

**Recommended dosage:**

For therapy of wounds, abscesses, and dental infections, 1-6 capsules for each 10 pounds body weight every 12 hours.

For therapy of osteomyelitis, 2-6 capsules for each 10 pounds body weight every 12 hours.

See package insert for complete product information.

**Warning**—Keep out of reach of children. Not for human use. Keep container tightly closed.

Store at controlled room temperature 20° to 25° C (68° to 77° F) [see USP].

**Each capsule contains:**  
Clindamycin hydrochloride equivalent to clindamycin, 25 mg.

812 771 108B  
5719-25/2

Made in Canada for  
Pharmacia & Upjohn Company  
Kalamazoo, MI 49001, U.S.A.  
By Pathcon V.M. Inc.  
Toronto, Ontario, M6B 1Y6  
Canada

NDC 0009-3043-01  
600 Capsules

**Antirobe®**  
Capsules

clindamycin hydrochloride  
capsules, USP

**25 mg**

Equiv. to 25 mg clindamycin

For Use in Dogs Only

**Caution:** Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

NADA #120-161, Approved by FDA

**Pharmacia  
& Upjohn**



Open Here ▶



Approved for use in dogs.

**Recommended dosage:**

For therapy of wounds, abscesses, and dental infections, 1-6 capsules for each 30 pounds body weight every 12 hours. For therapy of osteomyelitis, 2-6 capsules for each 30 pounds body weight every 12 hours.

See package insert for complete product information.

**Warning**—Keep out of reach of children.

Not for human use.

Keep container tightly closed.

Store at controlled room temperature 20° to 25° C (68° to 77° F) [see USP].

**Each capsule contains:**

Clindamycin hydrochloride equivalent to clindamycin, 75 mg.

812 765 106B

5719-26/2

NDC 0009-3044-01  
200 Capsules

**Antirobe®**  
Capsules

clindamycin hydrochloride  
capsules, USP

**75 mg**

Equiv. to 75 mg clindamycin

For Use in Dogs Only

**Caution:** Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

NADA #120-161, Approved by FDA



Open Here ➔

Made in Canada for  
Pharmacia & Upjohn Company  
Kalamazoo, MI 49001, USA  
By Parkeon Y.M. Inc.  
Toronto, Ontario, M8B 1Y5  
Canada

**Pharmacia  
& Upjohn**



Approved for use in dogs.

**Recommended dosage:**

For therapy of wounds, abscesses, and dental infections, 1-6 capsules for each 60 pounds body weight every 12 hours.

For therapy of osteomyelitis, 2-6 capsules for each 60 pounds body weight every 12 hours.

See package insert for complete product information.

**Warning**—Keep out of reach of children. Not for human use.

Keep container tightly closed.

Store at controlled room temperature 20° to 25° C (68° to 77° F) [see USP].

**Each capsule contains:**

Clindamycin hydrochloride equivalent to clindamycin, 150 mg.

812 774 106B

5719-21/2

Made in Canada  
Pharmacia & Upjohn Company  
Kalamazoo, MI 49001, USA  
By Parke-Davis Inc.  
Toronto, Ontario, M3B 1K5  
Canada

NDC 0009-3045-01

100 Capsules

# Antirobe®

Capsules

clindamycin hydrochloride capsules, USP

## 150 mg

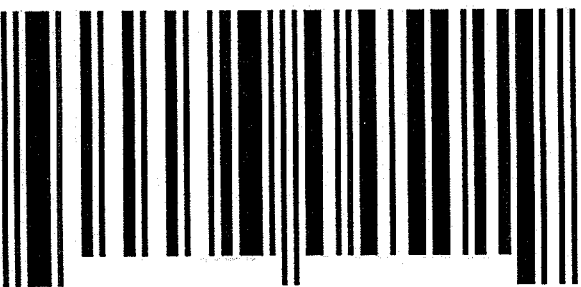
Equiv. to 150 mg clindamycin

**For Use in Dogs Only**

**Caution:** Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

NADA #120-161, Approved by FDA

Pharmacia  
& Upjohn



9 0009-3045-01 3

Open Here ➔





NDC 0009-3045-08  
100 Capsules

**ANTIROBE™**  
Capsules

clindamycin hydrochloride  
capsules, USP

150 mg

NDC 0009-3045-08  
100 Capsules

773627



**ANTIROBE™**  


Capsules  
clindamycin hydrochloride capsules, USP  
150 mg  
Equivalent to 150 mg clindamycin

For Use in Dogs Only

Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

NADA # 120-161 Approved by FDA

Made in Canada for  
Pharmacia & Upjohn Company  
Kalamazoo, MI 49001, USA  
By Parheon YM Inc.  
Toronto, Ontario  
M3B 1Y5 Canada



3 0009-3045-08 8



817 716 204B

See package insert for complete product information.  
Warning - Keep out of reach of children.  
Not for human use.  
Keep container tightly closed.  
Store at controlled room temperature 20°-25° C (68°-77° F) [see USP].  
Each capsule contains: Clindamycin hydrochloride equivalent to clindamycin, 150 mg.



Approved for use in dogs.  
**Recommended dosage:**  
For therapy of wounds, abscesses and dental infections, 1-6 capsules for each 60 pounds body weight every 12 hours.  
For therapy of osteomyelitis, 2-6 capsules for each 60 pounds body weight every 12 hours.



**Antirobe® 150 mg**  
clindamycin hydrochloride  
capsules, USP

Pharmacia & Upjohn Co.  
Kalamazoo, MI 49001  
LOT 000XX  
EXP 00/0000



0009304508

8054036000



**Antirobe® 150 mg**  
clindamycin hydrochloride  
capsules, USP  
Pharmacia & Upjohn Co.  
Kalamazoo, MI 49001  
LOT 000XX  
EXP 00/0000

**Antirobe® 150 mg**  
clindamycin hydrochloride  
capsules, USP

Pharmacia & Upjohn Co.  
Kalamazoo, MI 49001  
LOT 000XX  
EXP 00/0000



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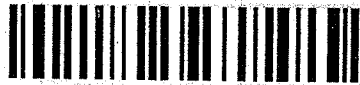
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LOT 000XX  
EXP 00/0000

NDC 0009-5015-01  
100 Capsules

**ANTIROBE™**  
Capsules

clindamycin hydrochloride  
capsules, USP

300 mg

NDC 0009-5015-01  
100 Capsules

773627



**ANTIROBE™**

Capsules  
300 mg  
clindamycin hydrochloride capsules, USP

Equivalent to 300 mg clindamycin  
For Use in Dogs Only  
Caution: Federal (USA) law restricts this drug to  
use by or on the order of a licensed veterinarian.  
NADA # 120-161 Approved by FDA

Made in Canada for  
Pharmacia & Upjohn Company  
Kalamazoo, MI 49001, USA  
By Partheon YM Inc.  
Toronto, Ontario  
M3B 1Y5 Canada



817 709 0001

See package insert for complete  
product information.  
Warning – Keep out of reach of children.  
Not for human use.  
Keep container tightly closed.  
Store at controlled room temperature 20°-25° C  
(68°-77° F) [see USP].  
Each capsule contains: Clindamycin  
hydrochloride equivalent to clindamycin, 300 mg.

Approved for use in dogs:  
**Recommended dosage:**  
For therapy of wounds, abscesses and dental  
infections, 1-6 capsules for each 120 pounds  
body weight every 12 hours.  
For therapy of osteomyelitis, 2-6 capsules for  
each 120 pounds body weight every 12 hours.



**Antirobe® 300 mg**  
clindamycin hydrochloride  
capsules, USP

Pharmacia &  
Upjohn Co.  
Kalamazoo, MI 49001

LOT 00XXX  
EXP 00/0000



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clindamycin hydrochloride  
capsules, USP

Pharmacia &  
Upjohn Co.  
Kalamazoo, MI 49001

LOT 00XXX  
EXP 00/0000



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capsules, USP

Pharmacia &  
Upjohn Co.  
Kalamazoo, MI 49001

LOT 00XXX  
EXP 00/0000



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